US ERA ARCHIVE DOCUMENT

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 3/16/84 OUT 04/27/8	4
Reviewed by James E. Wilson, Jr. Date 04/25/8	4
EPA Reg. No. or File Symbol 5389-6	noi en reine mine propries de comprese de proposition de propries modernes de la compresión de la compresión d
EPA Petition or EUP No. None	
Date Division Received 01/21/84	
Type Product(s): I,(D,) H, F, N, R, S	
Data Accession No(s) 252675	
Product Mgr. No. PM 32 (Castillo)	
Product Name Kay-5 Sanitizer	
Company Name Kay Chemical Company	
Submission Purpose Resubmission-Toxicity Data	
Chemical & Formulation	
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Active Ingredient(s)	8
Sodium dichloro-s-triazinetrione dihydrate	6.0
Trisodium phosphate	18.0

BACKGROUND

This product was initially registered with the signal word "Danger" based on the corrossiveness of the active ingredients when they are in high concentrations. The Agency advised the registrant at the time it recommended the signal word "Danger" that data could be submitted to determine the correct toxicity category. Subsequent to the initial acceptance of the first label a second label was accepted with the signal word "Warning." The acute data submitted will, if acceptable, indicate the correct toxicity cagetories.

<u>RECOMMENDATION</u>

Male rats and rabbits were tested in the acute oral and acute dermal studies. The acute dermal LD $_{50}$ for male rabbits is greater than 20.0g/kg. It does not appear that the study needs to be repeated using female animals. However, in the case of the acute oral study, it is recommended that the study be repeated using female rats since the acute oral LD $_{50}$ of the product is less than 5.0 g/kg.

The eye and skin irritation studies are acceptable and based on the results of those studies and the acute dermal study the product should be placed in the following toxicity categories:

Acute Dermal - 4 Skin Irritation - 4 Eye Irritation - 3

From the data reviewed the correct signal word appears to be "Caution". The statement "Do not get in eyes, on skin or on clothing" should be revised to read " Avoid contact with eyes." The First Aid statement for skin should be deleted.

DATA REVIEW

Acute Oral

Report by Biosearch, Inc. submitted to Kay Chemical Company, Greensboro, NC 27419, dated January 21, 1981. (Accession No. 252675)

- Method Five groups of male rats, each group containing 5 rats were fed doses of 0.5,1.0, 2.0, 4.0 and 8.0 g/kg body weight of the test material in a 20% w/v suspension in water. Body weight were averaged. Animals were observed for 14 days and each received a gross pathology examination.
- Results No deaths occurred in the lower three doses levels; at 4.0 and 8.0 g/kg all rats died. Lethargy, ruffled fur despression and drooling were the signs seen in animals which survived. Recovery was complete within 48 hours. The same signs including ataxia and convulsions were observed in the higher dose levels; deaths occurred within 2 hours. Gross pathology examination findings were unremarkable.

Conclusion - The acute oral LD₅₀ to male rats is 2.8 (2.0-4.0) g/kg.

Acute Dermal

Report by Biosearch, Inc. submitted to Kay Chemical Company, Greensboro, NC 27419, dated January 21, 1981. (Accession No. 252675).

- Method Four groups of male rabbits were used in the study.
 Each group contained 4 rabbits. Dose levels of
 4.0, 8.0, 16.0 and 20.0 g/kg body weight were applied
 to the abraded backs of the animals and remained in
 contact for 24 hours. All animals were observed for
 14 days; body weights were averaged. Gross pathology
 examinations were made on all rabbits.
- Results No unusual behavioral signs or mortality were noted. Gross pathology examination findings were unremarkable.
- Conclusion The acute dermal LD_{50} of this chemical is greater than 20.0 g/kg to male rabbits.

Skin Irritation

Report by Biosearch, Inc., submitted to Kay Chemical Company, Greensboro, NC 27419, dated January 21, 1981. (Accession No. 252675).

Method - A 0.5 g sample of the test material was applied to an intact an abraded site on 6 rabbis and remained there for 24 hours. The degree of irritation produced was evaluated after 24 and 72 hours.

Results - No irritation was observed at any site.

Conclusion - The product is not a skin irritant.

Eye Irritation

Reported by Biosearch, Inc., submitted to Kay Chemical Company, Greensboro, NC 27419, dated January 21, 1981. (Accession No. 252675).

- Method One-tenth gram of the test material was placed in the right eye of each of six rabbits. The eyes were examined 1,2,3,5, and 7 days after instillation.
- Results- Mild conjunctival irritation appeared in all one. Two eyes were completely clear of irritation by day two and all were clear by day three.
- Conclusion The chemical produces mild ocular irritation which clears within three days.